

REMARKS

The Official Action of April 10, 2003, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 1, 2, 4-6, 8, 9, 11 and 13, and these claims define patentable subject matter warranting their allowance. Accordingly, applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 1-3, 7, 10 and 12 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

First, applicants do not see that the statement of the rejection applies to claims 1 and 2. In other words, what is stated to be indefinite in the rejection does not appear in claims 1 and 2. Therefore, even if the rejection were correct, contrary to applicants' position, such rejection would not apply to claims 1 and 2.

In any event, applicants believe that the claims as originally drafted, when considered in light of applicants' specification (consistent with the law), would not have been confusing to those skilled in the art, and therefore the claims in their original form are fully in accordance with

Section 112. At **worst**, claim 3 and the claims dependent thereon in their previous form might be considered objectionable, but **only** as to form.

Nevertheless, in deference to the examiner's views and to minimize needless argument, and further based on the examiner's helpful suggestion, the terminology previously present in claim 3 has been cosmetically modified, and incorporated into claims 1 and 5, with claim 3 and the claims dependent thereon now having been deleted as redundant. The amendment of the language previously present in claim 3 is of a formal nature only, i.e. made to place the claims in better form consistent with the examiner's understanding of what is necessary or desirable under U.S. practice. Such amendment is not a "narrowing" amendment because the scope of previous claim 3 has not been reduced; the meaning remains the same.

Applicants respectfully request withdrawal of the rejection.

Claims 1, 2, 4-6, 8, 9, 11 and 13 have been rejected alternatively under Section 102 as anticipated by, or obvious under Section 103 from both Fernandez USP 5,820,879 and Dunn WO 97/04747, individually.<sup>1</sup> These four (4) rejections are

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<sup>1</sup> Applicants believe that the alternative rejections under Sections 102 and 103 are inconsistent. A claim cannot be both anticipated by and obvious from the same reference. If a reference anticipates a claim, then Section 103 is not only irrelevant, but makes no sense in conjunction with that reference, and vice versa.

respectfully traversed. However, applicants need not address these rejection at the present time, as the subject matter of claim 3 has been incorporated into claims 1 and 5, and the rejections have not been applied against claim 3.

Claims 1-3, 7, 10 and 12 have been rejected under Section 103 as obvious from Fernandez or Dunn in view of Rozenberg 2002/0064520. This rejection is respectfully traversed.

Applicants' slow-release composition which comprises nanospheres encapsulating the physiologically active substance, and which are encapsulated in liposomes having fusogenic capability derived from a Sendai virus, is simply not disclosed or made obvious by either Fernandez or Dunn, and the rejection appears to concede this point. (If this point is not conceded by the PTO, applicants request that the PTO point out where encapsulation in liposomes having fusogenic capability derived from a Sendai virus is to be found in either Fernandez or Dunn.) As understood, the rejection relies on Rozenberg as allegedly teaching the use of a Sendai virus for this purpose, and the rejection concludes that it would have been obvious to modify either or both of Fernandez and Dunn according to the teachings of Rozenberg, and thus obtain the claimed composition.

To the contrary, Rozenberg is unrelated to Fernandez and Dunn, and therefore the proposed combination would not have been obvious; and, even if it were obvious contrary to applicants' position, such a combination would not have resulted in claimed subject matter. Thus, the rejection focuses on the mention of Sendai virus in paragraph [0092] of Rozenberg, but the use of Sendai virus in Rozenberg is for gene delivery purposes, in particular to deliver the genetic content of MoMuLV to a novel host. The use of Sendai virus in the environment and for the purpose of Fernandez or Dunn is not made obvious by Rozenberg. Moreover, there is no reasonable expectation that any attempt to combine the diverse teachings of the references would lead to any useful result.

It should be noted that the fusogenic ability of liposomes can be derived from a Sendai virus by shaking a solution of the liposomes with Sendai virus at 37°C for two hours to react them. Please refer to the description from page 7, line 28 to page 8, line 3, and page 10, lines 13-15 of the specification. The fusogenic liposomes of the present invention may typically be formed by the method of Bangham et al. A patentable feature of the present invention resides in combining the use of nanospheres containing a physiologically active substance with a coating of liposomes having fusogenic ability derived from a Sendai virus. As explained from page

1, line 28, to page 9, line 12, of the specification, the advantages of the present invention are as follows:

(a) Sendai virus is inherently nonpathogenic in humans. In addition, if necessary, the virus can be illuminated with UV light so that the viral RNA is fragmented to ensure utmost safety.

(b) The fusogenic liposomes of the present invention are highly stable and easy to handle.

(c) An active substance can be efficiently introduced into the cytoplasm without causing injury to the functions of the cell membrane.

(d) The release profile of the introduced active substance in the cytoplasm can be controlled, and particularly, its slow release can be carried out.

To briefly summarize, the secondary reference is sufficiently diverse from the primary references so that the proposed combination would not have been obvious; moreover, there would have been no reasonable expectation of any successful result, so that the person of ordinary skill in the art would have had no reason to even try to put together any such combination. In addition, the advantages of the present invention pointed out above are unexpected, and again the prior art provides no reasonable expectation of such advantages.

Withdrawal of the rejection is in order and is respectfully requested.

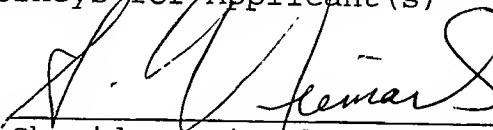
Claims 4-6, 8, 9, 11 and 13 have not been rejected under Section 103 as obvious from Fernandez or Dunn in view of Rosenberg. As the rejections based on Fernandez and Dunn alone are not applicable against these claims in view of the incorporation of the subject matter of claim 3 into claims 1 and 5, and as these claims have not been rejected as obvious from the proposed combination, it should follow that these claims are deemed by the PTO to define novel and unobvious subject matter under Sections 102 and 103. Claim 4 has now been rewritten in independent form.

Applicants respectfully request favorable consideration and formal allowance.

Respectfully submitted,

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